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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/155,327	03/29/99	CORY	S 11686

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EXAMINER	
KAUSHAL,S	
ART UNIT	**PAPER NUMBER**
1633	5

DATE MAILED: 07/17/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

PTO-90C (Rev. 2/95)

1- File Copy

U.S. G.P.O. 2000 ; 465-188/25268

Office Action Summary

Application No.	Applicant(s)
09/155,327	Cory et al
Examiner	**Group Art Unit**
SUMESH KAUSHAL	1633

☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1-20 is/are pending in the applicat

Of the above, claim(s) 6-20 is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-5 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 8, 12

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. Applicant's election with traverse of Group-I, claims 1-5, in Paper No. 6, 10/07/99 is acknowledged. The traversal is on the ground(s) that the separated groups are not independent and distinct. The applicant further argues that Group I & III, Group II & V, and Group IV & VI are related as products and the use of the product. This is not found persuasive for the reasons set forth in the restriction requirement mail 08/02/99.

The inventions listed as Groups I-VI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The isolated nucleic acid, polypeptide and an antibody are distinct from each other because they have different structure different modes of operation, different functions, or different effects. For example, the polypeptides can be isolated from cells endogenously expressing the polypeptide, rather than by recombinant means. Furthermore, polynucleotide can be used as probes, polypeptide can be used as an antigen to create immunity, and antibodies can be used to study cell surface expression of a protein. Thus, these products are distinct and are of independent uses.

In addition, the method of modulating Bcl-w expression by an antisense or nucleic acid molecules have different mode of operation than the method of modulating Bcl-w activity by a Bcl-w polypeptide or Bcl-w antibody. The Bcl-w polypeptides and antibody are biological active agents that can be administered without a carrier whereas gene need to be administered via a genetic vector. Biological active agents are active compounds whereas therapeutic gene must be efficiently expressed to cause therapeutic effect. Thus, inventions are distinct and are of separate uses.

The requirement is still deemed proper and is therefore made FINAL.

Claims 6-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 6, 10/07/99.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-5 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid comprising SEQ ID NO: 6 and 8 coding amnio acid sequences of SEQ ID NO: 7 and 9, does not reasonably provide enablement for an isolated nucleic acid comprising any and all derivatives of SEQ ID NO: 6 and 8 which has 47% or greater similarities to the amino acid sequence of SEQ ID NO: 7 and 9, and encodes a novel mammalian gene from the bcl-2 family. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention **commensurate in scope** with these claims.

The instant claims are drawn to an isolated nucleic acid (Bcl-w) comprising a novel mammalian gene from the bcl-2 family. The claims are drawn an isolated nucleic acid comprising derivatives of SEQ ID NO: 6 and 8 which has 47% or greater similarities to the amino acid sequence

of SEQ ID NO: 7 and 9. The claims are drawn to isolated nucleic acid molecule capable of hybridizing to nucleic acid sequences of SEQ ID 6 or 8 and encodes an amino acid sequence which has 47% or greater similarity to amino acid sequence set forth in SEQ ID NO: 7 and 9.

The specification disclosed SEQ ID NO: 6 and 8 that encodes the Bcl-w polypeptide. The specification further teaches that Bcl-w polypeptide belongs to Bcl-2 related proteins because it enhances the survival of the T hybridoma cells exposed to dexamethasone or irradiation (page 36, line 3-6; fig-5b). However, the specification as filed fails to disclose that any derivative of SEQ ID NO: 6 and 8 having 47% or greater similarity to amino acid sequence of SEQ ID NO: 7 and 9 elicits any Bcl-w related activity. It is known in the art that the bcl-2 signaling pathways are complex and have very divergent functions (specification page 2, line 4-25). The specification as filed fails to disclose any derivative of SEQ ID NO: 6 and 8 that enhances the survival of any cell by inhibiting programed cell death. The claimed derivative are simply computer generated hypotheses, wherein no biological function has been established. There is no description of mutational sites that exist in nature and there is no description of how the structure of putative Bcl-w derivatives relates to the structure and function of Bcl-2 related genes. Furthermore, it is general knowledge in the art that even conservative amino acid substitutions can adversely affect proper folding and biological activity if amino acids that are critical for such functions are substituted. Thus, it is not clear how one skilled in the art would use the invention as claimed for any specific purpose.

In view of the fact that there is no specific guidance or teaching for such in the specification as filed, it would require undue experimentation to practice the claimed invention. The quantity of experimentation required would include the functional characterization of any and all derivative of SEQ ID NO 6 and 8, and the role of deduced polynucleotide sequences as bcl-w activity.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

5. Claims 1, 4 and 5 are rejected under 35 U.S.C. 102(e) as being anticipated by Guastella (US 5,789,201 07/04/1998). Guastella teaches nucleotide sequences encoding a bcl-2 homolog (bcl-y) which matches 97.4% to SEQ ID NO: 6, 98.7% to SEQ ID NO: 7, 85.65 to SEQ ID NO:8 and 96.9% to SEQ ID NO:9 (see PTO sequence search report). Thus, the cited art anticipate the invention of instant claims.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sumesh Kaushal Ph.D. whose telephone number is (703) 305-6838. The examiner can normally be reached on Monday-Friday from 8:00 AM to 4:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor John L. LeGuyader can be reached on (703) 308-0447. The fax phone number for the organization where this application or proceeding is assigned as (703) 308-2035. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist whose telephone number is (703) 308-0196.

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